Lipose Corp.
Christine Emanuel
President
1205 De La Vina Street
Santa Barbara, California 93101

June 9, 2021

Re: K093067
Trade/Device Name: Lipose Disposable Cannula
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Christine Emanuel:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 29, 2009. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 29 2009

Lipose Corporation
% TECSA Technical Services, Inc.
Ms. Christine Emanuel
Regulatory Consultant
1205 De La Vina Street
Santa Barbara, California 93101

Re: K093067
Trade/Device Name: Lipose Disposable Cannulas
Regulation Number: 21 CFR 878-5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: September 09, 2009
Received: September 30, 2009

Dear Ms. Emanuel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093067 V1

Indications for Use

510(k) Number (if known): K093067

Device Name: Lipose Disposable Cannulas

Indications For Use:

The **Lipose Disposable Cannula** is intended for use in aesthetic body contouring.

Prescription Use ___x____ AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093067

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LIPOSE CORP.
DISPOSABLE CANNULA
510(k) Submission

DEC 2 9 2009

Section 5: 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21CFR § 807.92

Submitted by:

Lipose Corp.
280 Railroad Ave., Suite 200
Greenwich, CT. 06830 USA
Phone: 203-625-9700
Lee Miller, President
email: lee@reguluscapital.com
Fax: 203-625-9706

Contact Person for premarket notification:
Christine Emanuel, Regulatory Consultant
1205 De La Vina Street
Santa Barbara, CA 93101
Phone: 805.963.4312
Fax: 805.564.8642
Email: cemanuel@west.net

Date Prepared: September 28, 2009

Proprietary Name: Lipose Disposable Cannulas

Common Name: Liposuction Cannulas

Classification: Class II, MUU, 21 CFR 878.5040

Predicate Device: Tulip Biomed (formerly **Cell Bio-Systems, Inc., USA).** Tulip Disposable Cannula, 510(k) number K060089

Device Description: The Lipose Disposable Cannulas are coated stainless steel cannulas designed for connection to syringes (Luer Lock connector or hub adaptor). The cannulas are designed to be used with a syringe aspirator or syringe re-injector. There is also an infiltrator configuration available, to administer a solution to surgery sites pre-lipoplasty. The cannulas are made of hydrophilic coated stainless steel, and are available in various diameters, lengths and tip configurations.

The Lipose Disposable Cannulas are single-use disposables, supplied sterile (gamma radiation), packaged in a PETG tray sealed with a labeled or pre-printed Tyvek

lid.

Indication for Use: The **Lipose Disposable Cannula** is intended for use in aesthetic body contouring.

Technological Characteristics:

The design, use, and materials of the Lipose Disposable Cannulas and their predicate device are equivalent, in that all these cannulas are designed to be used for aesthetic body contouring and are fabricated out of stainless steel. Lipose Cannulas are all provided with a hydrophilic coating with lubricious properties as well, as are the Tulip Disposable Cannulas. No new technology or change in indications for use have been introduced by Lipose Corp. in the manufacture of the Disposable Cannulas. For these reasons, Lipose Corp. considers the use of the **Lipose Disposable Cannulas** to be substantially equivalent to their predicate device.